CLAIMS

1. A composition, for use and preparing a tablet by wet granulation, containing at least one quinoline carboxylic acid antibacterial agent and a stabilizer selected from the group consisting of inorganic acids such as hydrochloric, sulforic or phosphoric acid, or the group of oganic acids, such as anhydrous citric acid, hydrated citric acid, furmaric acid, malic acid, maleic acid, tartaric acid, glutaric acid, benzenesulfonic acid, benzoic acid or salicylic acid.

2. The composition of claim 1, wherein the stabilizer is anhydrous citric aicd.

3. The composition of claim 1 wherein the amount of the stabilizer is 10 to 35 % wt/wt.

4. The composition of claim 1 wherein the amount of the stabilizer is 20 to 35 % wt/wt.

5. The composition of claim 1 wherein the amount of the stabilizer is around 35 % wt/wt.

6. The composition of claim 1 wherein the quinoline carboxylic acid is norfloxacin.

7. The composition of claim 4 containing, by weight, about 60-75% norfloxacin, about 10-35% of a stabilizer.

8. The composition of claim 7 wherein the composition contains at least about 65 % by weight of norfloxacin.

9. The composition of claims 1 to 5 wherein the composition also contains inert diluents such as filler/binder, a disintegrant and/or a lubricant.

10. The composition of claim 9 wherein the composition contains about 5-15% of a binder/filler, 1-5% of a disintegrant and/or 0.5-2% of a lubricant.

11. The composition of claim 10 wherein the stabilizer is anhydrous citric acid, the filler/binder is a microcrystalline cellulose, the disintegrant is sodium starch glycollate and the lubricant is magnesium stearate.

12. A tablet prepared from the composition of claims 1 or 11.

13. A tablet of claim 12 which has a conventional film coating.

14. A method of preparing a tablet comprising a composition according to any of claims 1 to 11, which composition contains at least one quinoline carboxylic acid antibacterial agent and at least one stabilizer selected from the group consisting of inorganic acids or organic acids, comprising the steps of:

(i) granulating the antibacterial agent with the stabiliser dissolved in water, ethanol or a mixture of water/ethanol (10/90 to 90/10 v/v),

(ii) drying the obtained granules to a water content less than 3%, and

(iii) compressing the granules into a tablet.

15. The method according to claim 14, wherein the granules are dried at temperature range of 55°C - 65°C.

16. The method according to claim 14 or 15, wherein the method further comprises adding processing aids after step (ii) and before compressing.

17. The method according to any of claims 14 to 16, wherein the compressed tablet is film coated with a film forming system.

18. The method according to claim 17, wherein the film forming system is a modified cellulose, such as hydroxypropylcellulose and/or hydroxypropylmethylcellulose.

19. A tablet prepared by the method of claims 14 to 18.